

**Special 510(k) Summary of Safety and Effectiveness:
Modifications to the AVS® AL PEEK Spacer System**

Proprietary Name: AVS® ALign PEEK Spacer System **MAR 11 2010**

Common Name: Spinal Fixation Appliances

Proposed Regulatory Class: Class II

Intervertebral body fusion device
21 CFR 888.3080

Device Product Code: MAX

For Information contact: Kimberly Lane
Regulatory Affairs Specialist
2 Pearl Court
Allendale, NJ 07401
Telephone: (201) 760-8215
Fax: (201) 760-8415
Email: kimberly.lane@stryker.com

Date Summary Prepared: December 16, 2009

Predicate Device AVS® AL PEEK Spacers (K090166) and DePuy AcroMed, Inc.
Lumbar I/F Cage® with VSP Spine System: P960025 (i.e.,
Brantigan Cage)

Predicate Device Information The subject AVS® ALign PEEK Spacers and the predicate
AVS® AL PEEK Spacers and DePuy's Lumbar I/F Cage (i.e.,
Brantigan Cage) share similar design features:

- Hollow frame PEEK Implant
- Lateral fenestrations
- Serrations on the superior and inferior surfaces

Materials and mechanical testing results are similar between the
subject device and the listed predicates.

Description of Device Modification	<p>This Special 510(k) premarket notification is intended to introduce the new sizes to the AVS® AL PEEK Spacer family cleared under K090166.</p> <p>Note that the AVS® ALign PEEK Spacers may also be referred to as AVS® AL spacers.</p>
Intended Use	<p>The Stryker Spine AVS® ALign PEEK Spacers are intervertebral body fusion devices indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1.</p> <p>DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy.</p> <p>The AVS® ALign PEEK Spacers are to be implanted via anterior or anterolateral approach.</p> <p>The AVS® ALign PEEK Spacers are intended to be used with supplemental fixation plate and rod systems that have been cleared for use in the lumbosacral spine.</p>
Summary of the Technological Characteristics	<p>Testing in compliance with FDA's June 12, 2007 "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device" was performed for the AVS® ALign PEEK Spacers and demonstrated substantially equivalent performance characteristics to the identified predicate device systems.</p>



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

MAR 11 2010

Stryker Corporation
% Ms. Kimberly S. Lane
Regulatory Affairs Specialist
2 Pearl Court
Allendale, New Jersey 07401

Re: K093864

Trade/Device Name: AVS[®] Align PEEK Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: February 18, 2010
Received: February 19, 2010

Dear Ms. Lane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

Page 2 - Ms. Kimberly S. Lane

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson".

Mark N. Melkerson

Director

Division of Surgical, Orthopedic
And Restorative Devices

Office of Device Evaluation

Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K_____

Device Name: Stryker Spine AVS® ALign PEEK Spacers

Indications For Use:

The Stryker Spine AVS® ALign PEEK Spacers are intervertebral body fusion devices indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1.

DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy.

The AVS® ALign PEEK Spacers are to be implanted via anterior or anterolateral approach.

The AVS® ALign PEEK Spacers are intended to be used with supplemental fixation systems that have been cleared for use in the lumbosacral spine.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)Division of Surgical, Orthopedic,
and Restorative Devices510(k) Number K093864